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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/027,171	12/21/2001	John Gilbert	CVZ-002	9744

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LAHIVE & COCKFIELD, LLP.
28 STATE STREET
BOSTON, MA 02109

EXAMINER

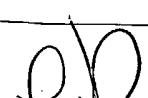
GORDON, BRIAN R

ART UNIT	PAPER NUMBER
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1743

DATE MAILED: 08/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/027,171	GILBERT ET AL.	
	Examiner	Art Unit	
	Brian R. Gordon	1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 July 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-64 is/are pending in the application.
- 4a) Of the above claim(s) 8-64 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3 and 7 is/are rejected.
- 7) ☒ Claim(s) 4-6 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 December 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>5-13-02; 7-23-02</u> . | 6) <input checked="" type="checkbox"/> Other: <u>IDS, 11-1-02</u> . |

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I, claims 1-7 in Paper filed July 29, 2004 is acknowledged. The traversal is on the ground(s) that: (1) the claims of at least groups I, III and IV are closely related and dependent; (2) a search of the groups would not be of serious burden to the examiner; (3) groups I, III, IV, VI share the same class 422; and (4) applicant states "Moreover, the patent statutes require that Applicants disclose how to make and use the system and method of the invention. It is only reasonable, then that Applicants be allowed to prosecute the system and the method for making and using the system in a single application. For example, claims 55-57 specifically recite a method for fabricating a liquid sample dispensing system. Claims 8-16 are directed to methods of using a liquid sample dispensing system. Therefore, it is improper to require that the subject matter of these groups be prosecuted in separate patent applications!" This is not found persuasive because Groups I, III, and IV are not dependent inventions. Interpreting each claim broadly reveals that each group is a different structure. Claim 1 is simply interpreted as two pins spaced apart coupled to holder and wherein at least one of the pins moveable with respect to the other. Unlike claim 40 neither pin is required to move about a pivot point or include fulcrum. The two arrangements are distinct. Neither claim 1 nor claim 40 requires the coating or acquisition region of claim 45. Claim 45 does not require the pivot point of claim 40 or the spacing of claim 1. The structural arrangements of the devices are distinct. As to searching each applicant is entitled to due process of a timely response and for the

examiner to search all of the distinct inventions of the instant application would hinder the effort to provide such due process to each applicant. As to the classification of the groups while the inventions may be broadly classified in class 422 the inventions obtain different subclassification resulting in a need to perform different searches for each group. While the statutes do require enablement of the invention under 112 first paragraph, the enablement is not related to the standards established for proper restrictions. The use of a system and how it is made are distinct from the structure itself. The structure may be manufactured or used in numerous ways (not limited to those of the specification). Each use and manufacturing process may be separately classified as in the instant case.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 8-64 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper filed July 29, 2004.

Specification

3. The spacing of the lines of the specification is such as to make reading and entry of amendments difficult. New application papers with lines double spaced on good quality paper are required.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by by Glover et al. US 4,659,677.

Glover discloses a pipette device 10 that holds two separate drop forming assemblies. Both drop forming devices comprise a tapered tip 24. Each tip can be moved relative to the other an actuator (300 and 302). The assemblies are not referred to specifically as pins, but the assemblies are structurally equivalent and function in the same manner as describe broadly by the claims. The drop of liquid formed at the tips is touched off on a suitable test element (column 5, line 51-53).

In another embodiment the device comprises a central rotating device that causes the distance between the tips to be varied (see figure 7).

The tips may separated at an appropriate distance in order to allow both tips to dipped into respective containers to allow for sampling (column 5, lines 8-22).

6. Claims 1-2 are rejected under 35 U.S.C. 102(b) as being by Feygin et al. US 5,957,167.

Feygin et al. discloses a method for handling and dispensing small volumes of liquid, and apparatus for carrying out the method. A small volume of liquid, which is retained within a fluid-dispensing member, is dispensed therefrom by accelerating, and then abruptly decelerating, the member.

Feygin further states that micro volume liquid dispensing systems are categorizable, generally, into one of two groups based on the way in which they

dispense their charge of liquid. In a first group of such micro volume delivery systems, a portion of the dispensable liquid, while still in its dispenser, is brought into contact with a receiving body ("the receiver"). Based on a difference in surface tension between liquid in the dispenser and liquid contacting the receiver, the liquid is drawn out of the dispenser and into the receiver. Such systems may be categorized as requiring "touch-off." Exemplary touch-off-based micro volume dispensing devices include capillary tubes, wettable pegs or pins and syringes using "drop touch-off," among others.

The dispenser incorporates a plurality of the aforementioned fluid-dispensing members, each capable of delivering a liquid volume in the range of about 0.5 to about 5 microliters. Preferably, the liquid carrier is configured to receive and retain its liquid charge via capillary action.

Fluid-dispensing member 200 has two opposed surfaces 202, 204 (may be considered pins) that are separated by gap 206. In one embodiment, surfaces 202 and 204 are concave. Such concave opposed surfaces can be obtained, for example, by forming a slit in a capillary tube. In a second embodiment, surfaces 202 and 204 are substantially flat. Such flat opposed surfaces can be obtained, for example, forming a slit in a solid rod. The dimensions of gap 206 and surfaces 202, 204 are suitably selected to allow aspiration and retention of a chosen liquid via a capillary effect.

Gap 206 having a dimension in the range of about 1 to about 1.5 millimeters (mm), and opposed surfaces 202, 204 having a width of about 1 mm or more are expected to be satisfactory for use with a wide range of liquids. Surfaces 202, 204 can be plastic or glass, and, may be suitably coated with noble metals, Teflon or the like.

In some embodiments, such as the exemplary embodiment shown in FIG. 3, the size of gap 206 is adjustable. Such adjustability is provided by gap adjuster 312.

Differences in dimensions between surfaces 202, 204, or between surface characteristics of surfaces 202, 204 resulting in local variations in surface tension may cause a deviation in the course of liquid issuing from a fluid-dispensing member. To reduce or eliminate any such deviation for those or other reasons, the fluid-dispensing member includes, in some embodiments, liquid director 412, such as is shown in FIG. 4. Liquid director 412, configured as a "needle-like" (could be considered a pin; therefore if each dispenser includes a pin then the pins are movable relative to each other) structure in the embodiment shown in FIG. 4, is disposed within gap 206 along a centrally-located long axis 1--1 of fluid-dispensing member 400. Liquid director 412 extends beyond opposed surfaces 202, 204 in the aforementioned axial direction.

The micro volume liquid dispenser further includes actuator 214 for moving/accelerating fluid-dispensing members 200, 300 or 400, and for stopping/decelerating the fluid-dispensing members, as shown conceptually in FIG. 5.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Feygin et al. or Glover et al. as applied to claim 1 above, and further in view of Garyantes, US 6,565,813, or in the alternative Pikarsky, US 6,455,352.

Feygin et al. nor Glover disclose the pins being fabricated from silicon.

Garyantes discloses a device for transferring fluids where the device has a plurality of pins that have been micromachined into the surface of a material such as glass, silicon or other crystalline material by a process selected from the group consisting of anisotropic, isotropic, plasma, or reactive ion etching and where the pins

have a circular, square, or other closed polygon face having a diameter of from 50 μm to 1 mm and the pins have a depth of 0.3 to 10 mm and where the device transfers a volume of fluid between 100 pl and 1 μl . Alternatively, the device could be electron discharge machined from metal or other conductive material; laser cut from any of the preceeding materials or a plastic; or molded from a plastic or glass or metal.

Pikarsky discloses an improved pin array assembly and method of manufacture of the pin array assembly. A pin array assembly includes a single crystal silicon wafer. The single crystal silicon wafer is formed to define a base and an array of pins. Each of the pins has a shaft and a tip surface. The pin shaft is hydrophobic and the pin tip surface is hydrophilic. The method of manufacture of the pin array assembly includes the steps of forming an initial shape of a single crystal silicon wafer to define a base and an array of pins. The initial shape of a single crystal silicon wafer is etched and the array of pins is polished. The step of forming an initial shape of a single crystal silicon wafer to define a base and an array of pins includes mechanically sawing the single crystal silicon wafer to define a base and an array of pins. Chemical treatment of the pins is performed to make the shaft of the pins hydrophobic and to make the pin tip surfaces hydrophilic.

It would have been obvious to one of ordinary skill in the art at the time of the invention to recognize that the pins of Feygin or Glover may be manufactured from silicon in order to allow for the pins to be chemically treated to aid in the fluid transfer process.

Allowable Subject Matter

11. Claims 4-6 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

12. The following is a statement of reasons for the indication of allowable subject matter: The prior art does not teach or fairly suggest a device comprising a sensor for sensing the separation distance and a sensor for measuring physical properties.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian R. Gordon whose telephone number is 571-272-1258. The examiner can normally be reached on M-F, with 2nd and 4th F off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

brg

Yelens Galkh
Yelens Galkh
primary examiner Au 1743